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(54) **CAROTID SHEATH WITH ENTRY AND TRACKING RAPID EXCHANGE DILATORS AND METHOD OF USE**

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604/160–161, 164.01, 164.1, 164.11,
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(56) **References Cited**

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U.S. PATENT DOCUMENTS

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4,224,937	A	9/1980	Gordon	
4,362,156	A	12/1982	Feller, Jr. et al.	
4,705,511	A	11/1987	Kocak	
4,748,982	A *	6/1988	Horzewski et al.	606/192
4,798,193	A *	1/1989	Giesy et al.	600/114
4,824,435	A *	4/1989	Giesy et al.	604/500
4,844,092	A *	7/1989	Rydell et al.	600/585
4,862,891	A	9/1989	Smith	
4,976,689	A	12/1990	Buchbinder et al.	

(Continued)

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FOREIGN PATENT DOCUMENTS

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US 2014/0288587 A1 Sep. 25, 2014

OTHER PUBLICATIONS

Related U.S. Application Data

International Search Report and Written Opinion dated Nov. 28, 2014
for PCT/US2014/052520.

(Continued)

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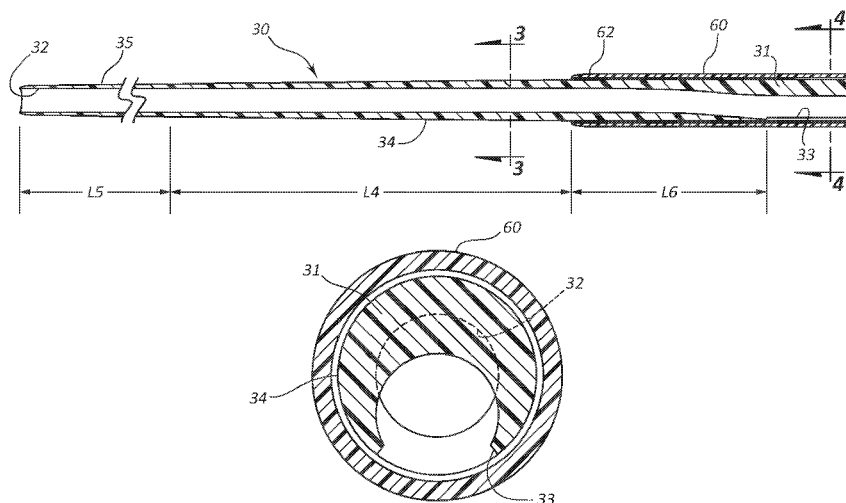
ABSTRACT

Dilators and sheaths for use in minimally invasive vascular
therapy are disclosed. In some embodiments, the dilators
include a slot that accesses a guidewire lumen within the
dilator. These slots facilitate rapid exchange of one dilator for
another. In another embodiment, a dilator is sufficiently stiff
to facilitate entry, but also designed to facilitate placement of
the dilator along a tortuous path.

(58) **Field of Classification Search**

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(56)

References Cited**U.S. PATENT DOCUMENTS**

4,997,421 A 3/1991 Palsrok et al.
 5,035,686 A * 7/1991 Crittenden et al. 604/103.05
 5,040,548 A * 8/1991 Yock 128/898
 5,061,273 A * 10/1991 Yock 606/194
 5,069,674 A 12/1991 Fearnot et al.
 5,135,535 A * 8/1992 Kramer 606/194
 5,149,330 A * 9/1992 Brightbill 604/523
 5,154,725 A * 10/1992 Leopold 606/194
 5,180,376 A 1/1993 Fischell
 5,324,262 A 6/1994 Fischell et al.
 5,324,269 A * 6/1994 Miraki 604/160
 5,360,432 A 11/1994 Shturman
 5,413,562 A 5/1995 Swauger
 5,417,669 A * 5/1995 Castaneda et al. 604/264
 5,423,774 A 6/1995 Fischell et al.
 5,443,457 A * 8/1995 Ginn et al. 604/528
 5,454,795 A 10/1995 Samson
 5,484,425 A 1/1996 Fischell et al.
 5,496,344 A 3/1996 Kanesaka et al.
 5,514,236 A 5/1996 Avellanet et al.
 5,531,721 A 7/1996 Pepin et al.
 5,630,806 A 5/1997 Inagaki et al.
 5,700,253 A 12/1997 Parker
 5,702,373 A 12/1997 Samson
 5,704,926 A 1/1998 Sutton
 5,796,044 A 8/1998 Cobian et al.
 5,827,230 A 10/1998 Bierman
 5,827,239 A 10/1998 Dillon et al.
 5,830,227 A * 11/1998 Fischell et al. 606/194
 5,849,016 A * 12/1998 Suhr 606/108
 5,863,366 A 1/1999 Snow
 5,879,499 A 3/1999 Corvi
 5,927,345 A 7/1999 Samson
 5,944,697 A 8/1999 Biche
 5,976,120 A 11/1999 Chow et al.
 5,976,154 A * 11/1999 Suhr 606/108
 6,007,522 A * 12/1999 Agro et al. 604/264
 6,036,715 A * 3/2000 Yock 606/194
 6,152,910 A * 11/2000 Agro et al. 604/523
 6,152,912 A 11/2000 Jansen et al.
 6,165,163 A 12/2000 Chien et al.
 6,338,725 B1 1/2002 Hermann et al.
 6,533,770 B1 3/2003 Lepulu et al.
 6,863,674 B2 3/2005 Kasahara et al.
 6,939,337 B2 9/2005 Parker et al.
 7,083,588 B1 8/2006 Shmulewitz et al.
 7,320,697 B2 1/2008 Demond et al.
 7,331,966 B2 2/2008 Soma et al.
 7,438,712 B2 10/2008 Chouinard
 7,618,430 B2 11/2009 Scheib
 7,655,021 B2 2/2010 Brasington et al.
 7,727,251 B2 6/2010 Spurchise et al.
 7,815,762 B2 10/2010 Lentz et al.
 7,905,877 B1 3/2011 Jimenez et al.
 8,034,045 B1 10/2011 Lyons

8,262,625 B1 9/2012 Fischell et al.
 8,747,428 B2 6/2014 Fischell et al.
 2001/0010247 A1 8/2001 Snow
 2001/0044633 A1 11/2001 Klint
 2001/0049517 A1 * 12/2001 Zadno-Azizi et al. 604/509
 2001/0056285 A1 * 12/2001 Dutta et al. 606/194
 2002/0058963 A1 * 5/2002 Vale et al. 606/200
 2002/0169377 A1 11/2002 Khairkhan et al.
 2003/0093060 A1 5/2003 Kempf
 2003/0199826 A1 * 10/2003 Windheuser et al. 604/161
 2003/0225365 A1 12/2003 Greff et al.
 2003/0229313 A1 12/2003 Bierman
 2004/0010243 A1 1/2004 Klint
 2004/0116960 A1 6/2004 Demond et al.
 2004/0153049 A1 8/2004 Hewitt et al.
 2004/0236346 A1 11/2004 Parker
 2005/0021022 A1 1/2005 Sturm et al.
 2005/0060017 A1 3/2005 Fischell et al.
 2005/0149060 A1 7/2005 Thorstenson et al.
 2005/0228479 A1 10/2005 Pavnik et al.
 2006/0064054 A1 3/2006 Sakakine et al.
 2006/0089618 A1 4/2006 McFerran et al.
 2006/0095050 A1 5/2006 Hartley et al.
 2006/0155302 A1 7/2006 Siskin et al.
 2007/0066958 A1 3/2007 Wright
 2007/0118207 A1 5/2007 Amplatz et al.
 2007/0185521 A1 8/2007 Bui et al.
 2007/0219500 A1 9/2007 Wright et al.
 2008/0051758 A1 2/2008 Rioux et al.
 2008/0097516 A1 4/2008 Chang et al.
 2009/0018525 A1 1/2009 Waite et al.
 2009/0054845 A1 2/2009 Puhasmagi et al.
 2009/0088790 A1 4/2009 Parodi et al.
 2009/0157162 A1 6/2009 Chow et al.
 2009/0234295 A1 9/2009 Lampropoulos et al.
 2009/0240202 A1 9/2009 Drasler et al.
 2009/0287182 A1 11/2009 Bishop et al.
 2009/0306591 A1 12/2009 Amisar et al.
 2009/0306603 A1 12/2009 Bierman et al.
 2010/0016837 A1 1/2010 Howat
 2010/0049168 A1 2/2010 Parker et al.
 2011/0160702 A1 6/2011 Jimenez et al.
 2011/0245775 A1 10/2011 Tekulve
 2012/0215174 A1 8/2012 Fischell et al.
 2012/0265282 A1 10/2012 Fischell et al.
 2013/0131718 A1 5/2013 Jenson et al.
 2013/0184735 A1 7/2013 Fischell et al.

OTHER PUBLICATIONS

U.S. Appl. No. 14/467,830, filed Aug. 25, 2014, Carlstrom et al.
 Notice of Allowance dated Feb. 28, 2014 for U.S. Appl. No. 13/349,060.
 International Search Report and Written Opinion dated Apr. 25, 2013 for PCT/US2013/020941.
 Office Action dated Jun. 3, 2013 for U.S. Appl. No. 13/349,060.
 Office Action dated Oct. 29, 2013 for U.S. Appl. No. 13/349,060.

* cited by examiner

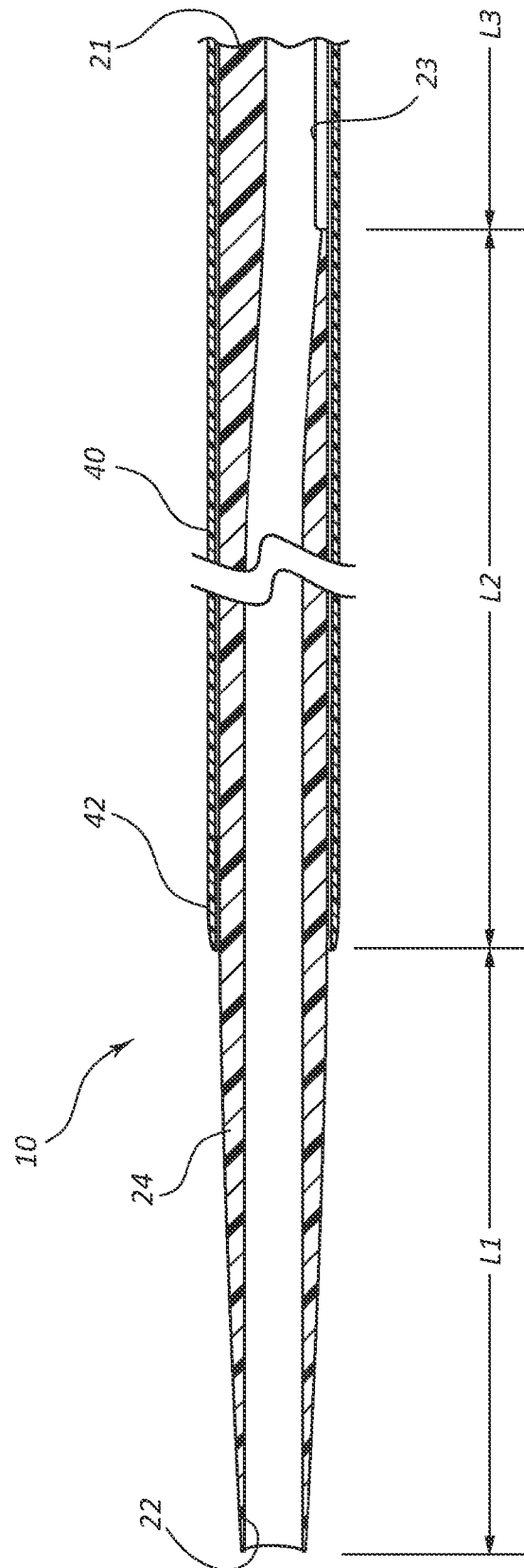


FIG. 1

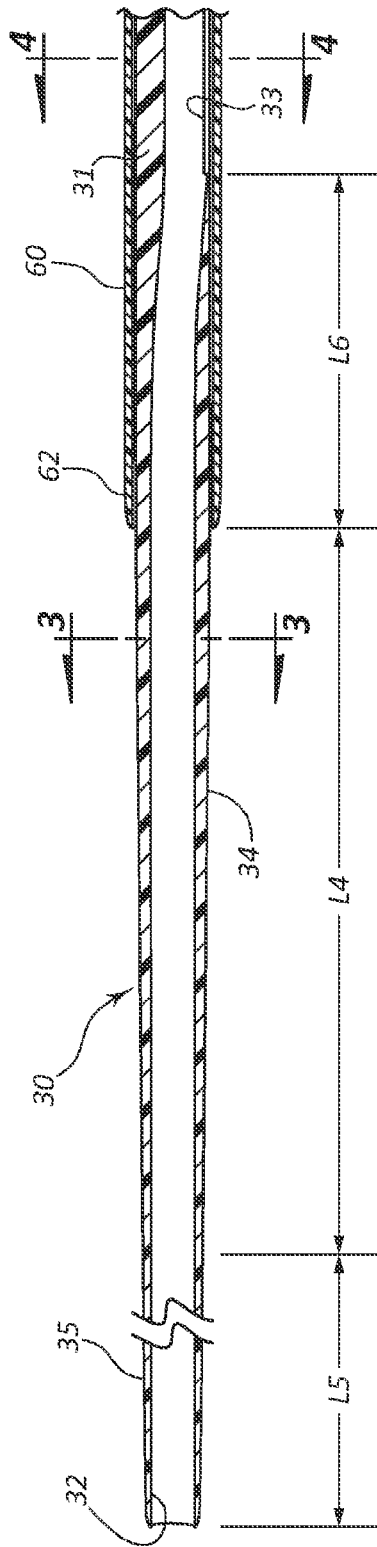


FIG. 2

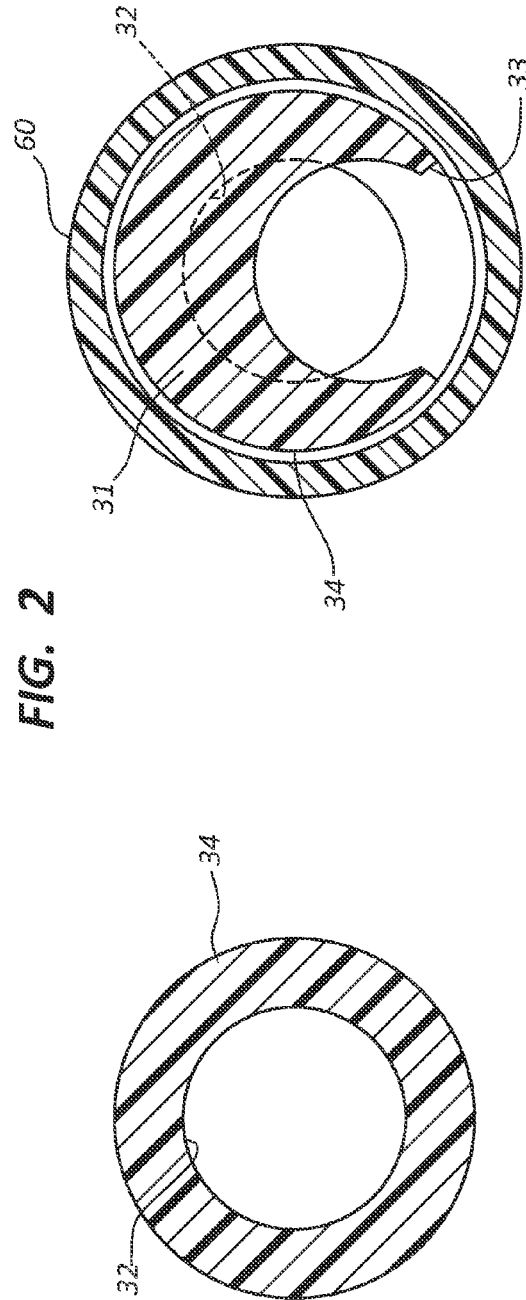


FIG. 3

FIG. 4

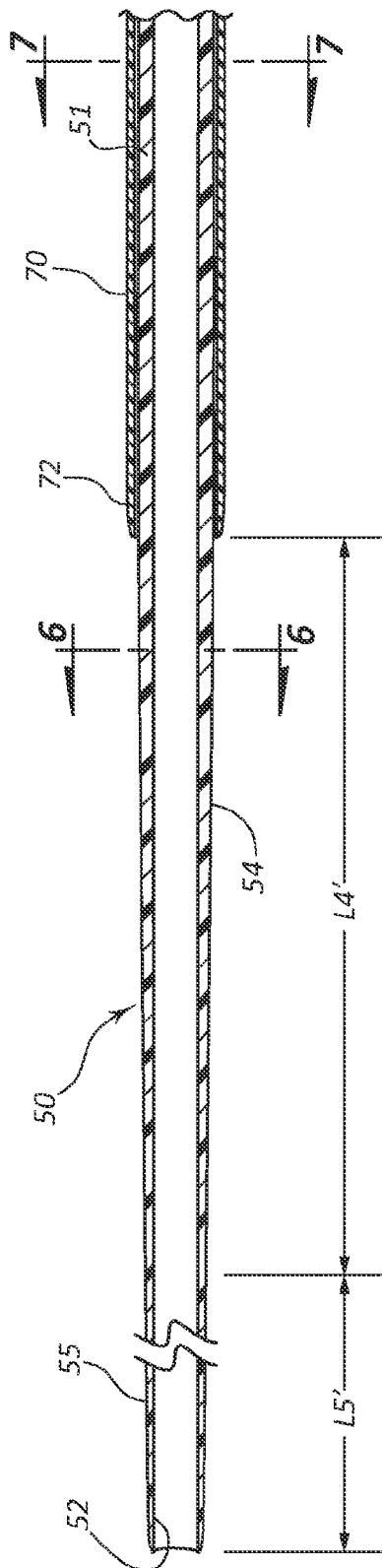


FIG. 5

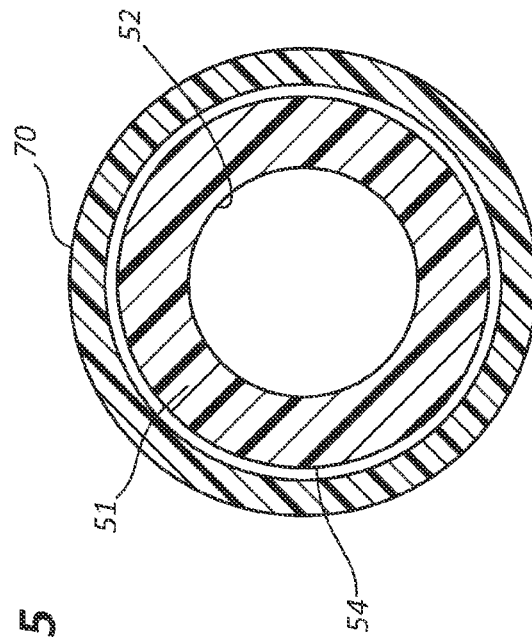


FIG. 7

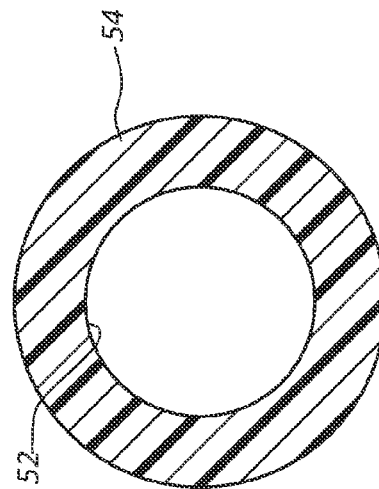


FIG. 6

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CAROTID SHEATH WITH ENTRY AND TRACKING RAPID EXCHANGE DILATORS AND METHOD OF USE

RELATED APPLICATIONS

This application is a continuation of pending U.S. patent application Ser. No. 13/349,060 filed on Jan. 12, 2012 and titled CAROTID SHEATH WITH ENTRY AND TRACKING RAPID EXCHANGE DILATORS AND METHOD OF USE, which is hereby incorporated by reference in its entirety.

TECHNICAL FIELD

The present disclosure relates generally to minimally invasive treatment devices such as sheaths, catheters, and dilators. More specifically, the present disclosure relates to sheaths, catheters, and dilators for use with treatments within the human vasculature, including the carotid artery.

BRIEF DESCRIPTION OF THE DRAWINGS

The embodiments disclosed herein will become more fully apparent from the following description and appended claims, taken in conjunction with the accompanying drawings. These drawings depict only typical embodiments, which will be described with additional specificity and detail through use of the accompanying drawings in which:

FIG. 1 is a longitudinal cross section of portions of one embodiment of a rapid exchange entry dilator and a carotid sheath.

FIG. 2 is a longitudinal cross section of one embodiment of a rapid exchange tracking dilator disposed within a carotid sheath.

FIG. 3 is a transverse cross sectional view of the tracking dilator of FIG. 2, taken through line 3-3.

FIG. 4 is a transverse cross sectional view of the tracking dilator of FIG. 2, taken through line 4-4.

FIG. 5 is a longitudinal cross section of a dilator disposed within a carotid sheath.

FIG. 6 is a transverse cross sectional view of a portion of the dilator of FIG. 5, taken through line 6-6.

FIG. 7 is a transverse cross sectional view of a portion of the dilator of FIG. 5, taken through line 7-7.

DETAILED DESCRIPTION

Catheters, sheaths, dilators, guidewires, and other treatment devices are used in connection with minimally invasive treatments and therapies, such as minimally invasive therapies within the human vasculature. The disclosure below relates specifically to, among other things, the placement and use of such devices to access and treat stenosis or other obstructions within the carotid artery. Notwithstanding these specific examples and references, the current disclosure is applicable to any treatment involving disposition of elongate devices within body lumens.

In some procedures, stents, balloons, filters, or other treatment devices are advanced within the vasculature of a patient through use of elongate catheters or sheaths. Furthermore, such sheaths or catheters can be placed, advanced, retracted, or moved in connection with dilators and/or guidewires. Specifically, in some instances, an elongate sheath or guiding catheter is disposed within the vasculature such that its distal end accesses a portion of the carotid artery. Such a sheath or guiding catheter may be designed to provide therapy within

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the vasculature or may be used as a conduit to advance other instruments, for example a catheter containing a stent or other treatment device, to the treatment site. In some instances, the sheath or guiding catheter is placed and positioned through use of dilators and/or guidewires. As used herein, a “carotid sheath” refers to a sheath or catheter configured to provide access to the carotid artery.

It will be readily understood that the components of the embodiments, as generally described and illustrated in the figures herein, could be arranged and designed in a variety of configurations. Thus, the following more detailed description of various embodiments, as represented in the figures, is not intended to limit the scope of the disclosure, but is merely representative of various embodiments. While the various aspects of the embodiments are presented in drawings, the drawings are not necessarily drawn to scale unless specifically indicated.

The phrases “connected to,” “coupled to,” and “in communication with” refer to any form of interaction between two or more entities, including mechanical, electrical, magnetic, electromagnetic, fluid, and thermal interaction. Two components may be coupled to each other even though they are not in direct contact with each other. For example, two components may be coupled to each other through an intermediate component.

The terms “proximal” and “distal” refer to opposite ends of a medical device. As used herein, the proximal end of a medical device is the end nearest a practitioner while the practitioner is using or manipulating the device, while the distal end is the opposite end. For example, the proximal end of a catheter or sheath used in minimally invasive vascular treatment is the end accessible to a practitioner during use, while the distal end is disposed within a patient during use.

The “axial direction” of an elongate component refers to a direction along the center axis of the elongate component.

In some instances, a practitioner accesses the carotid artery by an entry point in the femoral artery. A relatively small catheter and/or guidewire can then be advanced from the femoral artery to the aortic arch, and from the aortic arch to either the right or left common carotid artery (in some instances via the innominate artery in the case of the right common carotid artery). Access to the internal or external carotid arteries is generally gained via either common carotid artery. The initial catheter and/or guidewire can then be used to help position subsequent stiffer catheters or guidewires.

An access path from the aortic arch to either common carotid artery, and any subsequent branch thereof, can be relatively tortuous. In some instances, carotid sheaths configured to act as conduits for stent delivery devices are relatively stiff and thus difficult to position within this tortuous path. Inability to properly place a carotid sheath can make minimally invasive stenting impossible, thus resulting in more invasive procedures such as surgical endarterectomy.

An exemplary procedure includes first gaining access to the vascular system through the femoral artery at the groin. In some instances, a needle and/or a guidewire is utilized at this step. A physician then advances a guidewire and/or a diagnostic catheter (e.g., a small catheter size 5 or 6 French) from the entry point to the aortic arch, then from the aortic arch to the common carotid artery. In some instances, the guidewire and/or diagnostic catheter is further advanced into the internal or external carotid arteries. The diagnostic catheter can then be utilized to advance a stiff guidewire to the treatment site. During the course of some procedures, the distal end of the stiff guidewire remains anchored in one of these distal positions during the treatment. In an exemplary procedure, a physician then uses an entry and/or a tracking dilator to intro-

duce and advance a sheath into the entry point and to a position just proximal of the treatment location. Such positioning of the sheath allows a practitioner to utilize the sheath to advance treatment devices, such as balloons, stents, and so on, to the treatment site. In some instances, the sheath is very stiff. In such instances, use of a tracking dilator to advance the relatively stiff sheath can reduce the risk that the sheath will cause the distal end of the stiff guidewire to become displaced from its anchor location.

As further described below, in some embodiments, one or more dilators are utilized in connection with advancing a carotid sheath to a treatment location. As used herein, "dilator" refers to an elongate instrument that may be configured to be disposed within an elongate sheath, the dilator configured to guide the sheath as the sheath is advanced along a path. In some embodiments, the dilator is relatively stiff or resilient to aid in advancing the dilator and/or sheath beyond points of high resistance, such as through an arterial wall at the access point (for example, in instances where scar tissue or calcification make access particularly difficult). Some dilators include lumens configured to accommodate other instruments such as guidewires. Moreover, in certain of the embodiments described below, a dilator includes features configured to facilitate rapid exchange between dilators. For instance, as detailed below, some dilators within the scope of this disclosure include a slot to facilitate rapid exchange. Rapid exchange is utilized, for example, in instances where a first dilator is used primarily for entry (an "entry dilator"), while a second dilator is used to advance a sheath along a distal tortuous path, such as from the aortic arch to the carotid artery (a "tracking dilator").

FIG. 1 is a longitudinal cross section of portions of one embodiment of a rapid exchange entry dilator **10** and a carotid sheath **40**. As illustrated, the distal end of each component is positioned to the left of the proximal end. In the illustrated embodiment, only a portion (adjacent the distal ends) of each component is shown, as indicated by the cut-away lines on the right side of the drawing.

The illustrated entry dilator **10** includes an elongate main body **21** configured to be disposed within the carotid sheath **40**. The carotid sheath **40** is configured with a radiopaque marker band **42**, which in some embodiments is positioned at or adjacent the distal end of the carotid sheath **40**. The entry dilator **10** of FIG. 1 further includes a central lumen **22** configured to accommodate a guidewire (not shown). In some embodiments the central lumen **22** is sized to accommodate particular sizes of guidewires, such as guidewires from about 0.012 inches to about 0.038 inches, including guidewires from about 0.018 inches to about 0.032 inches and from about 0.022 inches to about 0.028 inches.

In some embodiments the entry dilator **10** and the carotid sheath **40** are displaceable with respect to each other in the axial direction of each component. During certain therapies, however, the two components are advanced or retracted within the vasculature together, meaning the two components are moved as a unit, without axial displacement with respect to each other. Additionally, some instances, the two components are advanced by a combination of moving the components together and displacing them with respect to each other.

In embodiments where the entry dilator **10** and the carotid sheath **40** are advanced together, distance **L1** is the length of the portion of the entry dilator **10** that extends from the distal end of the carotid sheath **40**. In some embodiments **L1** is from about 2 cm to about 8 cm in length, including lengths from about 3 cm to about 7 cm and lengths from about 4 cm to about 6 cm. Because, in certain embodiments, the entry dilator **10** is displaceable with respect to the carotid sheath **40**, distance **L1**

may not be a constant value, but rather represent a general parameter. In other embodiments, **L1** represents the maximum distance the entry dilator **10** is configured to extend from the carotid sheath **40**. In other words, in some examples, the entry dilator **10** is configured to be displaceable with respect to the carotid sheath **40**, up to a certain point, but can further include a coupling mechanism (e.g., a luer fitting on the proximal end) configured to limit the maximum displacement of the distal end of the entry dilator **10** with respect to the carotid sheath **40**.

In some embodiments, the entry dilator **10** includes an eccentrically located slot **23**. (A transverse cross sectional view of an analogous slot in another embodiment of a dilator is also shown in FIG. 4.) As further outlined below, the slot **23** of FIG. 1 is configured to facilitate rapid exchange of the entry dilator **10** with another dilator. In the illustrated embodiment, the slot **23** is configured as an elongate opening in the sidewall of the entry dilator **10** that is in communication with the central lumen **22**. The slot **23** extends to the proximal end of the entry dilator **10**. Distance **L2** shown in FIG. 1 represents the distance from the distal end of the carotid sheath **40** to the beginning of the slot **23**. In other words, **L2** is the length of the entry dilator **10** that is disposed within the carotid sheath **40** but does not include the slot **23**. In some embodiments **L2** is from about 5 cm to about 15 cm, including embodiments from about 7 cm to about 12 cm and from about 9 cm to about 11 cm.

The illustrated entry dilator **10** has a tapered portion **24** adjacent the distal end of the entry dilator **10**. In some embodiments the tapered portion **24** is configured to extend completely from the carotid sheath **40**; that is, in some embodiments the tapered portion **24** has a length of **L1**. In other embodiments the tapered portion **24** is longer or shorter than **L1**.

In the illustrated embodiment, distance **L3** corresponds to the length of the entry dilator **10** and carotid sheath **40** from the distal end of the slot **23** to the proximal end (not shown) of the carotid sheath **40**. In some embodiments the entry dilator **10** extends proximally from the proximal end of the carotid sheath **40**, while in other embodiments it is flush with or shorter than the carotid sheath **40** at the proximal end. In some embodiments **L3** is from about 60 to 100 cm, including embodiments from about 70 cm to 90 cm and embodiments from about 75 cm to about 85 cm. In certain embodiments, the carotid sheath **40** includes a luer fitting at the proximal end, including luers that are coupleable to a Touhy-Borst fitting.

In the illustrated embodiment, entry dilator **10** is configured to facilitate entry into the vasculature. For example, in some embodiments entry dilator **10** is relatively stiff (compared to, for example, the tracking dilator described below) in order to facilitate entry through calcified arteries, such as the femoral artery. In certain embodiments, the entry dilator **10** is thus composed of a relatively stiff material, for example, polypropylene or nylon. Moreover, in some embodiments the material used for the dilator has a durometer hardness equal to or greater than 50 on the Shore D scale, including materials having a hardness from about 50 to about 80 on the Shore D scale, or materials having a hardness from about 60 to about 70 on the Shore D scale.

FIG. 2 is a longitudinal cross section of a tracking dilator **30** disposed within a carotid sheath **60**. While FIG. 1 illustrates the entry dilator **10** and FIG. 2 illustrates the tracking dilator **30**, certain elements and subcomponents of each can, in certain respects, resemble elements and subcomponents of the other. It will be appreciated that all the illustrated embodiments may have analogous features. Accordingly, the relevant descriptions of such features apply equally to the features of

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the tracking dilator **30** and the related components of FIG. **2**. Any suitable combination of the features, and variations of the same, described with respect to the components illustrated in FIG. **1** can be employed with the components of FIG. **2**, and vice versa. Furthermore, analogous or substantially analogous features shown in one figure may or may not be designated by a reference numeral regardless of whether the analogous feature is so designated in the analogous figure. This pattern of disclosure applies equally to further embodiments and components described herein.

FIG. **2** shows the tracking dilator **30** disposed within a carotid sheath **60**. As with the carotid sheath **40** of FIG. **1**, the carotid sheath **60** of FIG. **2** includes a radiopaque marker band **62**. In the illustrated embodiment, the tracking dilator **30** includes a main body **31** with a central lumen **32** disposed within the main body **31**. In some embodiments, the central lumen **32** is configured to accommodate a guidewire, analogous to the central lumen **22** of FIG. **1**. Furthermore, the tracking dilator **30** shown in FIG. **2** includes an eccentrically placed slot **33**. In the illustrated embodiment, the slot **33** is located a distance, **L6**, from the distal end of the carotid sheath **60**. In some embodiments **L6** is from about 60 to 100 cm, including embodiments from about 70 cm to 90 cm and embodiments from about 75 cm to about 85 cm. Like the slot **23** of FIG. **1**, the slot **33** of the tracking dilator **30** of FIG. **2** extends from the position shown to the proximal end (not shown) of the tracking dilator **30**.

As further detailed below, in some embodiments, the tracking dilator **30** is configured to facilitate access to relatively tortuous portions of the vasculature. For example, in some procedures, a relatively small-diameter needle is inserted into the femoral artery at the access point and a thin guidewire is inserted through the needle. In the exemplary procedure, the needle is then removed and an entry dilator (such as **10** from FIG. **1**) is advanced along the guidewire. As described above, the entry dilator **10** of FIG. **1** is relatively stiff, allowing it to be forced through the artery wall or through calcified tissue in the artery, thereby providing fuller access to the vasculature. In some instances the entry dilator **10** is then exchanged for the tracking dilator **30** in order to traverse tortuous paths within the vascular, for example, traversing from the aortic arch to the common carotid artery or beyond. In some procedures, the carotid sheath **40** is advanced with the tracking dilator **30**.

In some embodiments, the slot **23**, **33** of the dilator **10**, **30** facilitates rapid exchange of one dilator **10**, **30** for another. For example, in some procedures where a practitioner wishes to replace dilator "A" disposed within the body with dilator "B," slots on each dilator facilitate this exchange. In this example, a guidewire is disposed within dilator A. If dilator A were to be removed over the proximal end of the guidewire, the length of guidewire disposed outside the body would need to be longer than the total length of dilator A, in order to allow a practitioner to remove the dilator while still being able to directly grasp (or otherwise secure) the guidewire. A slot in the dilator, however, allows the practitioner to decouple the dilator from the guidewire via the slot, allowing the practitioner to maintain direct contact with the guidewire near the insertion point. Only the distal-most portion of dilator A (having no slot) would need to be fed over the proximal end of the guidewire. Similarly, when the practitioner replaces dilator A with dilator B, the distal end (having no slot) of dilator B can be slid over the proximal end of the guidewire while the rest of the dilator could be fed onto the guidewire via the slot. Thus, as long as the guidewire extends from the patient a distance greater than the length of the non-slotted portions of

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each dilator, a practitioner can quickly exchange dilators while maintaining secure contact with the guidewire near the insertion point.

The features of tracking dilator **30** of FIG. **2** are configured to facilitate advancement of the tracking dilator **30** along relatively tortuous paths. In some embodiments, the tracking dilator **30** includes a cylindrical portion **35** adjacent the distal end of the tracking dilator **30**. The cylindrical portion **35** defines a constant outside diameter along its length, **L5**. **L5** is from about 3 cm to about 15 cm in some embodiments, including embodiments from about 5 cm to about 12 cm and embodiments from about 7 cm to about 11 cm. Furthermore, in some embodiments, the cylindrical portion **35** is formed in a relatively thin walled design, the wall of the dilator being less than 0.025 inches in some instances, including wall thicknesses of less than 0.020 inches, less than 0.015 inches, and less than 0.010 inches. Moreover, the tracking dilator **30** of some embodiments is composed of a relatively soft material, for example an elastomer with a durometer hardness that is less than or equal to 45 on the Shore D scale. In some instances, the tracking dilator **30** is softer than, for example, an entry dilator, such as the entry dilator **10** of FIG. **1**, or a carotid sheath, such as the carotid sheaths **40**, **60** of FIGS. **1** and **2**.

In certain procedures, the softness of the tracking dilator **30** and/or the thin walled design of the cylindrical portion **35** facilitates advancement of the tracking dilator along a tortuous path. Stiffer dilators, for example the entry dilator **10** of FIG. **1**, may be more difficult to advance over relatively tortuous paths. Furthermore, the design of the tracking dilator **30** may lower the risk of displacing the distal end of a guidewire used to place the tracking dilator **30**, as compared to stiffer dilators.

In some embodiments, the tracking dilator **30** includes a tapered portion **34** adjacent the cylindrical portion **35**. In the illustrated embodiment, the tapered portion **34** is configured as a transition portion between the more pliable cylindrical portion **35** and the stiffer proximal portion of the tracking dilator **30**. In the exemplary embodiment, the tracking dilator **30** thus has a pliable tip to facilitate advancement of the tracking dilator **30** along a difficult path while also having a stiffer portion along the length of the tracking dilator **30**. This stiffer portion is configured to facilitate in advancing the relatively stiff carotid sheath **60** to the treatment location. In some embodiments, the tapered portion **34** has a length, **L4**, from about 5 cm to about 30 cm, including lengths from about 10 cm to about 20 cm and from about 12 cm to about 17 cm. Furthermore, in some embodiments the tapered portion **34** is tapered along its entire length or is cylindrical along a portion of its length and tapered along another portion of its length.

In some embodiments, the tracking dilator **30** is formed of a radiopaque material, for example an elastomeric material with tungsten particles deposited therein. Similarly, the entry dilator **10** of FIG. **1** is formed of a radiopaque material in some embodiments.

FIG. **3** is a transverse cross sectional view of the tracking dilator **30** of FIG. **2**, taken through line **3-3**. This view illustrates the sidewall of the tracking dilator **30** in the tapered portion **34**. In some embodiments, the central lumen **32** is located substantially along the central axis of the tracking dilator **30**. Similarly, in some embodiments, the central lumen **22** of the entry dilator **10** of FIG. **1** is located along the central axis of the entry dilator **10**.

FIG. **4** is a transverse cross sectional view of the tracking dilator **30** of FIG. **2**, taken through line **4-4**. FIG. **4** illustrates the position of the slot **33** within the main body **31** of the tracking dilator **30**. FIG. **4** also shows the axial positioning of

the tracking dilator **30** within the carotid sheath **60**. FIG. **4** illustrates how, in some embodiments, the slot **33** is eccentrically positioned within the main body **31** of the tracking dilator **30**. As also shown in FIG. **2**, the slot **33** of the illustrated embodiment is in communication with the central lumen **32**. The relationship between the slot **33** and the central lumen **32** may be understood as the central lumen **32** extending the entire length of the tracking dilator **30**, with the central lumen **32** radially centered near the distal tip of the tracking dilator **30** and eccentrically positioned such that the central lumen **32** crosses the sidewall to the outside surface of the dilator (forming the slot **33**) along the remaining length of the tracking dilator **30**. Thus, the portion of the central lumen **32** that forms the slot **33** is only a partial lumen, as it is an open, or slotted, portion. In other embodiments the central lumen **32** is radially centered along the length of the tracking dilator **30**, with the slot **33** extending from the central lumen **32** through the sidewall of the tracking dilator **30**. The slot **23** of the entry dilator **10** of FIG. **1** may be similarly positioned as described in each embodiment described in connection with the slot **33** and the tracking dilator **30** of FIG. **2**.

An exemplary procedure utilizing the entry and tracking dilators **10**, **30** described in connection with FIGS. **1-4** begins by a physician first gaining access to the vascular system through the femoral artery at the groin. In some instances, a needle and a thin guidewire are used to initially pierce the wall of the artery. In this example, the thin guidewire is then used to advance a diagnostic catheter and/or a stiff guidewire to the treatment site. The physician then advances the entry dilator **10** along the stiff guidewire, the entry dilator **10** configured to push through calcified tissue at the entry site. In some instances the stiff guidewire extends all the way to, or beyond, a treatment site; for example, it may be anchored in the internal or external carotid arteries. Further, in some instances, the thin guidewire is initially advanced to, or beyond, the treatment site, and obviates the need for a stiff guidewire.

In this example, the guidewire and/or the entry dilator **10** is then used to advance the carotid sheath **40** such that it provides access to the treatment site. In some embodiments the distal end of the carotid sheath **40** will be positioned just proximal to the treatment site. In some instances, the carotid sheath **40** is relatively stiff, such that advancing the carotid sheath **40** along the guidewire poses a significant risk the guidewire will become displaced or dislodged, including instances where the distal end of the guidewire is moved from its anchor location. Thus, in some embodiments, the entry dilator **10** is used to advance the carotid sheath **40** to the treatment site and to mitigate the risk of dislodging the guidewire. In procedures where the path to the treatment site is relatively non-tortuous, an entry dilator **10** (with sufficient length to guide the carotid sheath **40** all the way to the treatment site) can be used to fully advance the carotid sheath **40**.

In some instances, the tortuous path between the entry site and the treatment site renders the entry dilator **10** too stiff to facilitate advancement of the carotid sheath **40**. Thus, in some embodiments, a practitioner exchanges the entry dilator **10** for a tracking dilator **30**, then advances the carotid sheath **40** along the tracking dilator **30**. (Note: in this example, the tracking dilator **30** of FIG. **2** may be used in connection with the same carotid sheath **40** as the entry dilator **10** of FIG. **1**. Carotid sheath **40** can thus be used in place of carotid sheath **60** in connection with the tracking dilator **30**.) This is done by advancing the tracking dilator **30** and the carotid sheath **40** along the guidewire, with the tracking dilator **30** protruding from the distal end of the carotid sheath **40**. In some embodiments the tracking dilator **30** is softer than the carotid sheath

40 and is configured to facilitate advancement of the carotid sheath **40** along tortuous paths, such as from the aortic arch to either common carotid artery or beyond. Once the carotid sheath **40** is positioned, the practitioner then performs the remaining steps of the therapy, for example placing a stent.

In some embodiments where the entry dilator **10** is used prior to the tracking dilator **30**, the slots **23**, **33** are configured to allow rapid exchange of one dilator **10**, **30** for the other. In some embodiments, the slots **23**, **33** allow a practitioner to remove or insert a dilator **10**, **30** while still grasping the guidewire relatively close to the entry site. As described above, if no slot **23**, **33** were present, the length of the guidewire that extends proximally from the entry site would need to be longer than the total length of the dilator **10**, **30** in order to allow a practitioner to directly grasp (or otherwise secure) the guidewire while removing the dilator **10**, **30**. In some embodiments, the slots **23**, **33** are configured to allow the practitioner to decouple the dilator **10**, **30** from the guidewire as the dilator **10**, **30** is removed from the patient's body, without the need to feed the entire dilator **10**, **30** over the proximal end of the guidewire. Thus, in some instances, the "rapid exchange" nature of these dilators **10**, **30** reduces the risk that exchanging dilators **10**, **30** will dislodge or displace the guidewire, as the practitioner is more able to maintain the stability and position of the guidewire due to the practitioner's ability to secure the guidewire near the entry point.

Furthermore, in some embodiments the distal end of the carotid sheath **40**, **60** includes a hydrophilic coating. The outer surface of the entry and/or tracking dilator **10**, **30** also includes a hydrophilic coating in some embodiments. This coating reduces friction, facilitating exchange of dilators **10**, **30** and advancement of the carotid sheath **40**, **60** along the dilators **10**, **30**.

FIG. **5** is a longitudinal cross section of a dilator **50** disposed within a carotid sheath **70**. The carotid sheath **70** includes a radiopaque marker band **72**. Similar to FIGS. **1** and **2**, FIG. **5** illustrates the distal portions of the dilator **50** and the carotid sheath **70**; the proximal ends are not shown. Any dilator **10**, **30**, **50** disclosed herein may be used in connection with any carotid sheath **40**, **60**, **70**.

The illustrated dilator **50** is configured with a central lumen **52** positioned at a radially centered position in both the distal portion of the dilator **50** and a main body **51** of the dilator **50**, unlike the lumens (**22**, **32**) of the entry and tracking dilators **10**, **30** that are eccentrically placed (and form slots **23**, **33**) along a portion of the dilators **10**, **30**.

In some embodiments, the dilator **50** is configured with a cylindrical portion **55** adjacent the distal end of the dilator **50**. This cylindrical portion **55** defines a length, L_5' . L_5' is from about 3 cm to about 15 cm in some embodiments, including embodiments from about 5 cm to about 12 cm and embodiments from about 7 cm to about 11 cm. Furthermore, in some embodiments, the cylindrical portion **55** is formed in a relatively thin walled design, the wall of the dilator **50** being less than 0.025 inches in some instances, including wall thicknesses of less than 0.020 inches, less than 0.015 inches, and less than 0.010 inches.

Further, in the illustrated embodiment, the dilator **50** includes a tapered portion **54**. The tapered portion **54** defines a length, L_4' , from about 5 cm to about 30 cm, including lengths from about 10 cm to about 20 cm and from about 12 cm to about 17 cm in some embodiments. Furthermore, like the tapered portion **34** of FIG. **2**, in some embodiments the tapered portion **54** is tapered along its entire length or is cylindrical along a portion of its length and tapered along another portion of its length.

FIGS. 6 and 7 are transverse cross sectional views of portions of the dilator 50 of FIG. 5. FIG. 6 illustrates how the central lumen 52 may be axially centered within the tapered portion 54, while FIG. 7 illustrates how the central lumen 52, dilator body 51, and carotid sheath 70 may be concentrically positioned.

In some procedures, the dilator 50 is configured for use in place of both the entry dilator 10 and tracking dilator 30. For instance, if a patient does not have significant scar tissue or calcification at the entry site (for example, patients who have not had prior vascular surgery), a relatively stiff entry dilator may not be necessary. In such instances the dilator 50 of FIG. 5 is sufficiently stiff to allow for initial entry and subsequent guiding of the carotid sheath 70. Additionally, the dilator 50 is sufficiently pliable, particularly as related to the thin walled, cylindrical portion 55, to facilitate advancement of the dilator 50 along a difficult path for certain procedures. This design thus obviates the need for multiple dilators and the exchange of dilators in some instances. The dilator 50 herein described may be used in place of the entry dilator 10, the tracking dilator 30, or both in any of the exemplary procedures described above.

Any of the dilators 10, 30, 50 described herein may be composed of any elastomer or other material, including radiopaque materials such as plastics containing tungsten particles. Further, in some embodiments the dilator 10, 30, 50 is configured with a radiopaque marker band positioned at some point along the dilator 10, 30, 50, for example near the distal end. In some embodiments the radiopaque marker band is formed of a platinum alloy.

Moreover, in some embodiments any of the dilators 10, 30, 50 herein described may be configured with a coating to provide lubrication between the dilator 10, 30, 50 and the carotid sheath 40, 60, 70 thus aiding in the advancement of the carotid sheath 40, 60, 70 along the dilator 10, 30, 50.

The examples and embodiments disclosed herein are to be construed as merely illustrative and exemplary, and not as a limitation of the scope of the present disclosure in any way. It will be apparent to those having skill in the art with the aid of the present disclosure that changes may be made to the details of the above-described embodiments without departing from the underlying principles of the disclosure herein.

The invention claimed is:

1. A method of manipulating a sheath assembly to place a sheath within the vasculature of a patient, the method comprising:

obtaining a sheath assembly comprising,
an elongate sheath;

an entry dilator comprising:

an elongate main body extending from a proximal end of the dilator to a distal end of the dilator, the elongate main body comprising:

a proximal portion extending longitudinally from the proximal end of the dilator; and

a distal portion directly adjacent to and extending longitudinally from a distal end of the proximal portion of the elongate main body to the distal end of the dilator;

a lumen disposed within the elongate main body, the lumen defining a distal opening at the distal end of the elongate main body; and

a slot extending from the lumen through a sidewall of the entry dilator, the slot extending longitudinally in a proximal direction from a proximal end of the distal portion of the dilator along the remaining length of the dilator;

wherein a lumen wall along the distal portion forms a continuous and unbroken ring; and

a tracking dilator comprising:

an elongate main body extending from a proximal end of the dilator to a distal end of the dilator, the elongate main body comprising:

a proximal portion extending longitudinally from the proximal end of the dilator; and

a distal portion directly adjacent to and extending longitudinally from a distal end of the proximal portion of the elongate main body to the distal end of the dilator;

a lumen disposed within the elongate main body, the lumen defining a distal opening at the distal end of the elongate main body;

a non-tapering cylindrical portion adjacent the distal end of the elongate main body; and

a slot extending from the lumen through a sidewall of the entry dilator, the slot extending longitudinally in a proximal direction from a proximal end of the distal portion of the dilator along the remaining length of the dilator;

wherein a lumen wall along the distal portion forms a continuous and unbroken ring;

inserting the entry dilator and sheath into the vasculature of a patient such that a first portion of a guidewire is disposed within the lumen of the entry dilator and a second portion of the guidewire is disposed proximal of the entry dilator;

removing the entry dilator from the vasculature of the patient without removing the first portion of the guidewire from the vasculature of the patient;

inserting the tracking dilator over the guidewire and into the sheath; and

advancing the tracking dilator and sheath into or within the vasculature of the patient.

2. The method of claim 1, wherein

removing the entry dilator from the vasculature of the patient comprises decoupling the entry dilator from the second portion of the guidewire; and

the second portion of the guidewire is not longer than the entry dilator.

3. The method of claim 1, wherein removing the entry dilator from the vasculature of the patient without removing the guidewire from the vasculature of the patient comprises decoupling the entry dilator from the guidewire via the slot of the entry dilator.

4. The method of claim 1, wherein removing the entry dilator from the vasculature of the patient without removing the guidewire from the vasculature of the patient comprises maintaining direct contact with the second portion of the guidewire while the entry dilator is removed from the guidewire.

5. The method of claim 4, wherein removing the entry dilator from the vasculature of the patient without removing the guidewire from the vasculature of the patient further comprises removing the first portion of the guidewire from the lumen of the entry dilator via the slot of the entry dilator.

6. A method of manipulating a sheath assembly, the method comprising:

inserting an entry dilator and sheath into the vasculature of a patient such that a first portion of a guidewire is disposed within a lumen of the entry dilator and a second portion of the guidewire is disposed proximal of the entry dilator, wherein the entry dilator comprises:

a proximal portion extending longitudinally from a proximal end of the dilator; and

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a distal portion directly adjacent to and extending longitudinally from a distal end of the proximal portion of the elongate main body to a distal end of the dilator; wherein a lumen wall along the distal portion forms a continuous and unbroken ring;

removing the entry dilator from the vasculature of the patient without removing the first portion of the guidewire from the vasculature of the patient, wherein removing the entry dilator from the vasculature of the patient comprises decoupling the entry dilator from the second portion of the guidewire via a slot of the entry dilator, wherein the slot extends longitudinally in a proximal direction from a proximal end of the distal portion of the dilator along the remaining length of the dilator;

inserting a tracking dilator over the guidewire and into the sheath; and

advancing the tracking dilator and sheath into or within the vasculature of the patient.

7. The method of claim 6, wherein the second portion of the guidewire is not longer than the entry dilator.

8. The method of claim 6, wherein removing the entry dilator from the vasculature of the patient without removing the guidewire from the vasculature of the patient comprises maintaining direct contact with the second portion of the guidewire while the entry dilator is removed from the guidewire.

9. The method of claim 8, wherein removing the entry dilator from the vasculature of the patient without removing the guidewire from the vasculature of the patient further com-

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prises removing the first portion of the guidewire from the lumen of the entry dilator via the slot of the entry dilator.

10. A method of placing a sheath within the vasculature of a patient, the method comprising:

- 5 inserting an entry dilator and sheath into the vasculature of a patient; the entry dilator including a first slot in a sidewall, wherein the entry dilator comprises:
 - 10 a proximal portion extending longitudinally from a proximal end of the dilator; and
 - a distal portion directly adjacent to and extending longitudinally from a distal end of the proximal portion of the elongate main body to a distal end of the dilator, wherein a lumen wall along the distal portion forms a continuous and unbroken ring;
 - 15 the entry dilator is positioned over a guidewire; and the first slot extends longitudinally in a proximal direction from a proximal end of the distal portion of the dilator along the remaining length of the dilator;
 - 20 removing the entry dilator;
 - inserting a tracking dilator including a second slot in a sidewall into the sheath without removing the guidewire; and
 - 25 advancing the tracking dilator and sheath into the vasculature.
11. The method of claim 10, wherein the guidewire is partially removed from the entry dilator via the first slot.
12. The method of claim 10, wherein the guidewire is partially removed from the tracking dilator via the second slot.
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